INSTITUTE: National Institute of Arthritis and Musculoskeletal and Skin Diseases

STUDY NUMBER: 91-AR-0196 PRINCIPAL INVESTIGATOR: James D. Katz, M.D.

STUDY TITLE: Studies on the Natural History and Pathogenesis of Polymyositis; Dermatomyositis, and Related Diseases

Continuing Review Approved by the IRB on 01/06/15
Amendment Approved by the IRB on 07/29/15 (AA) Date Posted to Web: 07/31/15
Healthy Volunteer

INTRODUCTION

We invite you to take part in a research study at the National Institutes of Health (NIH).

First, we want you to know that:

Taking part in NIH research is entirely voluntary.

You may choose not to take part, or you may withdraw from the study at any time. In either case, you will not lose any benefits to which you are otherwise entitled. However, to receive care at the NIH, you must be taking part in a study or be under evaluation for study participation.

You may receive no benefit from taking part. The research may give us knowledge that may help people in the future.

Second, some people have personal, religious or ethical beliefs that may limit the kinds of medical or research treatments they would want to receive (such as blood transfusions). If you have such beliefs, please discuss them with your NIH doctors or research team before you agree to the study.

Now we will describe this research study. Before you decide to take part, please take as much time as you need to ask any questions and discuss this study with anyone at NIH, or with family, friends or your personal physician or other health professional.

You are being asked to participate in a study designed to advance our knowledge about diseases with inflammation in the muscles.

The evaluation will consist of a brief history and magnetic resonance imaging (MRI). This is a sensitive diagnostic tool which uses a strong magnetic field and radio waves to show changes in tissue. There is no radiation risk. You will lie on a table in a space enclosed by a metal cylinder (the scanner itself). The time required to stay in the cylinder will be about 20-30 minutes. During part of the time, you will be asked to lie very still.

Discomforts and Risks: Patients are at risk for injury from MRI if they have metal objects in their bodies such as a pacemaker, aneurysm clips (metal clips on the wall of a large artery), metallic prostheses, cochlear implants, or shrapnel fragments. Welders and metal workers are also at risk for eye injury because of unsuspected tiny metal fragments there.

Individuals with fear of confined spaces may become anxious during MRI. You will hear a thumping noise created by the radio waves forming the images. You will feel no pain, but you may find the noise and the closed-in space discomforting.

You will be observed at all times by the operators and will be able to speak to them; you can be moved out of the machine at your request.

It is possible that an abnormality you did not know about will be detected by the MRI. If so, we will tell you about it and tell your physician about it so that further care can be provided by your physician**.**

You may also be asked to have a study called a positron emission tomography (PET) combined with MRI scan. We are obtaining these scans in healthy individuals to compare them to scans from patients with muscle disease. Our hope is this will allow us to better diagnose the type of muscle disease patients have, prevent future patients from having to undergo invasive procedures to obtain diagnosis, better understand the activity of the patients' disease, and to try and find other non-muscle parts of the body that may be affected by myositis.

This scan is very similar to the MRI, but in addition you will be injected with a radioactive agent, FDG, by intravenous line. After the placement of the intravenous line and injection of the FDG you will be asked to sit quietly in a room for approximately 1 hour. Then you will be asked to lay flat on a raised bed looking up toward the ceiling. Once you are resting on the bed you will notice it will move periodically through the PET/MRI machine which is a large cylinder. You will need to rest in a still position so that we can take the proper images of you. You will hear periodic soft banging noises while the scan is happening. These noises are the magnets moving in the cylinder. The scan should take approximately 2 hours. During the scan you will be able to talk to the individual operating the PET/MRI machine and will have an emergency button you can press to stop the machine.

There may be no direct benefit to you from participating in this study. There is the potential for a benefit to patients with muscle disease from your participation by helping to improve the scientific community's understanding of muscle disease.

Discomforts and Risks: This test includes all of the discomforts and risks of a normal MRI which are described above. In addition it involves the administration of a radioactive intravenous agent and placement of an intravenous line. The major risks of the intravenous line placement are bleeding, infection, bruising, and local discomfort. There is the potential this test could reveal an abnormality that would lead to you pursuing further testing with your primary care physician and that you could suffer adverse events from that additional testing.

This research study involves exposure to radiation from 1 PET/MRI scan using 10 mCi of the radioactive agent, FDG. This radiation exposure is not required for your medical care and is for research purposes only. The amount of radiation you will receive in this study is 0.63 rem which is below the guideline of 5 rem per year allowed for research subjects by the NIH Radiation Safety Committee. The average person in the United States receives a radiation exposure of 0.3 rem per year from natural sources, such as the sun, outer space, and the earth's air and soil. If you would like more information about radiation, please ask the investigator for a copy of the pamphlet, An Introduction to Radiation for NIH Research Subjects.

While there is no direct evidence that the amount of exposure received from participating in this study is harmful, there is indirect evidence it may not be completely safe. There may be a very slight increase in the risk of cancer.

Please tell your doctor if you have had any radiation exposure in the past year, either from other research studies or from medical tests or care, so we can make sure that you will not receive too much radiation. Radiation exposure includes x-rays taken in radiology departments, cardiac catheterization, and fluoroscopy as well as nuclear medicine scans in which radioactive materials were injected into your body.

If you are pregnant or breast feeding you will not be permitted to participate in this part of the research study. It is best to avoid radiation exposure to unborn or nursing infants since they are more sensitive to radiation than adults.

If we detect an abnormality on this test we will notify you and your physician about it so that further care can be provided by your physician. If you do not want your physician notified of any abnormalities please request this in writing and we will not notify your physician of any findings.

The PET/MRI is completely voluntary.

Handling of your information and data:

Your imaging and medical data will be kept in a secure password protected database and will be kept indefinitely. We will not store any blood or tissue samples. Your history will be recorded in the NIH clinical system and your images will be stored in the NIH clinical imaging database. Due to the clinical nature of this data we will be unable to destroy it.

In the future research projects may arise where your images could be useful. We ask you to designate below whether or not your images can be used for those projects. Any future research use will require approval by the institutional review committees whose purpose it is to ensure research protects the rights and welfare of human research subjects.

Please initial by the line indicating your wishes:

_____I allow my images to be used for future studies **unrelated** to this protocol by other groups of investigators without being contacted. These images will be coded so only investigators in the original protocol can identify the images as being of you.

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_____ I wish to be re-contacted if further studies with my images are considered. After the study has been explained, I will then decide if I want my images to be included.

_____Under no circumstances shall my images be used for any future studies.

If we study your images in the future and find abnormalities, do you wish to be contacted?

_____YES _____NO

For questions and concerns regarding the research participation of this protocol, please call the Clinical Center's Patient Representative at (301) 496-2626.

Withdrawal

At any point in this study you can ask to be withdrawn. If you withdraw from the study we will cancel all future appointments you have with us and we will not contact you in the future. The investigators on this trial may also withdraw you from the trial if they feel it is unduly dangerous due to your current condition or if it is decided you no longer qualify for the protocol. If you are unable to complete the PET/MRI or do not wish to complete the PET/MRI you will be withdrawn from the study. If you withdraw from this trial it will not affect your participation in any other NIH study.

Collaboration

We currently have no arranged collaborations for this protocol. If you agreed to have your images shared for future studies your images will be coded before being used and all other personally identifiable information will be removed. The code will be kept locked in the office of the principal investigator of this trial. This person will be the only one with access to it. We will maintain a code system so that only patients appropriate to be used for any other studies you have given us permission to use your images for would be sent to those studies. By using a code system if new findings are made we will be able to contact you to inform you of those findings. All images that are sent to collaborators will be kept in a secured manner.

Conflict of Interest

The National Institutes of Health reviews NIH employees at least yearly for conflicts of interest. The following link contains details on this process http://ethics.od.nih.gov/forms/Protocol-Review-Guide.pdf. You may ask your research team for additional information or a copy of the Protocol Review Guide.

This protocol may have investigators who are not NIH employees. They are expected to comply with their Institution's conflict of interest policies.

OTHER PERTINENT INFORMATION

1. Confidentiality. When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

The Federal Privacy Act protects the confidentiality of your NIH medical records. However, you should know that the Act allows release of some information from your medical record without your permission, for example, if it is required by the Food and Drug Administration (FDA), members of Congress, law enforcement officials, or authorized hospital accreditation organizations.

2. Policy Regarding Research-Related Injuries. The Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the National Institutes of Health, the Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

3. Payments. The amount of payment to research volunteers is guided by the National Institutes of Health policies. In general, patients are not paid for taking part in research studies at the National Institutes of Health. Reimbursement of travel and subsistence will be offered consistent with NIH guidelines.

4. Problems or Questions. If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, James D. Katz, M.D. Building: 10, Room 6F-216F, Telephone: (301) 594-0529.

You may also call the Clinical Center Patient Representative at 301-496-2626.

5. Consent Document. Please keep a copy of this document in case you want to read it again.

COMPLETE APPROPRIATE ITEM(S) BELOW:

A. Adult Patient's Consent

I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby consent to take part in this study.

Signature of Adult Patient/Legal Representative _____ Date _____

Print Name _____

B. Parent's Permission for Minor Patient.

I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby give permission for my child to take part in this study.
(Attach NIH 2514-2, Minor's Assent, if applicable.)

Signature of Parent(s)/Guardian _____ Date _____

Print Name _____

C. Child's Verbal Assent (If Applicable)

The information in the above consent was described to my child and my child agrees to participate in the study.

Signature of Parent(s)/Guardian _____ Date _____ Print Name _____

THIS CONSENT DOCUMENT HAS BEEN APPROVED FOR USE FROM JANUARY 6, 2015 THROUGH JANUARY 5, 2016.

Signature of Investigator _____ Date _____

Print Name _____

Signature of Witness _____ Date _____

Print Name _____